REMARKS/ARGUMENTS

Claims 1 and 3-13 remain in the application. Claims 1, 3, 9, 10, and 13 have been amended. Claim 2 has been canceled. Minor amendments have been made to the specification. Reconsideration of this application, as amended, is respectfully requested.

The specification has been amended as follows:

(1)   The number of a reference has been amended.

(2)   The definitions relating to the determination of the concentration of an analyte have been deleted.

(3)   The repeated phrase "based on" has been deleted.

(4)   The repeated phrase "user that" has been deleted.

Claim 1 has been amended to specify that the method can be used to determine the value of a physiological parameter. Support for this amendment can be found at page 8, lines 4-9 of the specification.

Claim 3 has been amended to insert the missing word "least".

Claim 9 has been amended to insert the word "optical" before the word "data."

Claim 13 has been amended to correct an antecedent basis error.

Claims 4, 9, and 13 were rejected under 35 U. S. C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. This rejection is respectfully traversed for the following reasons.

Because claim 1 has been amended to recite value of physiological parameter as an addition to concentration of analyte, claim 4 now conforms to claim 1, because blood pressure is a physiological parameter. Accordingly, the rejection of claim 4 based on 35 U. S. C. §112, second paragraph, can be withdrawn. Claim 9 has been amended to insert the word "optical" before the word "data." Thus, it is clear that the claim further limits the collecting step. Accordingly, the rejection of claim 9 based on 35 U. S. C. §112, second paragraph, can be withdrawn. Claim 13 has been amended to correct an antecedent basis error. Accordingly, the rejection of claim 13 based on 35 U. S. C. §112, second paragraph, can be withdrawn.

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Claims 1, 3-10, and 13 were rejected under 35 U. S. C. §101 on the ground that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. This rejection is respectfully traversed for the following reasons.

The utility of the invention claimed in the present application is set forth at page 5, lines 19-26 of the specification, where it is stated:

> The invention provides a safeguard against inclusion of erroneous data resulting from an inadvertent movement of a body part with respect to a measuring probe in a non-invasive optical measurement. Inclusion of erroneous data in the subsequent calculation of the concentration of a metabolite or of the determination of a disease state will lead to erroneous results and erroneous intervention that may adversely affect the health of a patient. Thus, the primary benefit of this invention is the generation of accurate and reliable data for the purpose of clinical diagnosis.

In view of the foregoing explanation, it is submitted that the rejection under 35 U. S. C. §101 can be withdrawn.

Claims 1, 5-9, and 10 were rejected under 35 U. S. C. §102 (b) as being anticipated by Hall (U. S. 4,955,379). This rejection is respectfully traversed for the following reasons.

Hall, U. S. Patent No. 4,955,379 (hereinafter "Hall"), discloses a pulse oximeter apparatus comprising a bandpass filter adapted selectively to exclude motion artifact from wanted signal.

Claim 1 requires the steps of collecting **optical** data from the tissue over a selected periods of time, introducing the collected data into an algorithm to identify an artifact in the **optical** data, and determining whether an artifact has appeared in the **optical** data. Hall does **not** disclose the use of **optical** data. Accordingly, Hall does not anticipate claim 1 or the claims depending from claim 1.

Claims 3 and 4 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Hall in view of Ukawa et al. (US 5,485,838). This rejection is respectfully traversed for the following reasons.

Ukawa et al., U. S. Patent No. 5,485,838 (hereinafter "Ukawa et al." discloses a non-invasive blood pressure measurement device including: a cuff, a pressure detector for detecting a cuff pressure; a cuff pressure control pump for linearly increasing or decreasing the cuff pressure; a light-emitting member for injecting a beam of light into a part of a body by the cuff; light-receiving members for detecting an amount of light transmitted or an amount of light reflected of the beam of light injected into the body from the light-emitting member; a demodulating circuit for separating the pulsatile component from the light-receiving signal obtained fro the light-receiving members; a CPU for sending a control; signal to the cuff pressure control pump to thereby either increase the cuff pressure if it is judged that the pulsatile component has not been detected before applying pressure to the cuff based on the detection output from the demodulating circuit or decrease the once increased cuff pressure, and detecting an inflection point in the light-receiving signal in the course of increasing or decreasing the cuff pressure to thereby output a cuff pressure at the inflection point as a mean pressure value of a subject who is in systemic hypotension.

Claims 3 and 4 depend from claim 1. As stated previously, Hall does **not** disclose the use of **optical** data. <u>Neither</u> Hall <u>nor</u> Ukawa et al. discloses that the appearance of artifacts can be determined in **optical** data. The rejection based on the combination of Hall and Ukawa et al. is improper because the success of that combination could not have been predicted in the absence of Applicants' disclosure. Thus, the rejection based on the combination of Hall and Ukawa et al. is a hindsight reconstruction of the prior art, which reconstruction could have been perceived only after seeing the Applicants' disclosure. It is impermissible to use the inventor's disclosure as a "road map" for selecting and combining prior art disclosures. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among <u>isolated</u> disclosures in the prior art to deprecate the

claimed invention. For this reason, the combination of Hall and Ukawa et al. is impermissible, and, consequently, that combination cannot render claims 3 and 4 obvious to one of ordinary skill in the art. Accordingly, the combination of Hall and Ukawa et al. fails to render claims 3 and 4 obvious to one of ordinary skill in the art.

Claims 2, 11, and 12 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Hall in view of Pologe et al. (US 5,766,127). This rejection is respectfully traversed for the following reasons.

Pologe et al., U. S. Patent No. 5,766,127 (hereinafter "Pologe et al.") discloses a method and apparatus for the monitoring perfusion of the tissue by arterial blood. An optical path length change is calculated for a number of digitized samples of a received light intensity signal generated by a photo detector that receives light directed into a patient's tissue by one or more light emitting diodes or laser diodes. The optical path length changes are summed over a predetermined time such as one half cardiac cycle or other set interval to generate a perfusion index.

Claims 2, 11, and 12 depend from claim 1. As stated previously, Hall does **not** disclose the use of **optical** data. Neither Hall nor Pologe et al. discloses that the appearance of artifacts can be determined in **optical** data. The rejection based on the combination of Hall and Pologe et al. is improper because the success of that combination could not have been predicted in the absence of Applicants' disclosure. Thus, the rejection based on the combination of Hall and Pologe et al. is a hindsight reconstruction of the prior art, which reconstruction could have been perceived only after seeing the Applicants' disclosure. It is impermissible to use the inventor's disclosure as a "road map" for selecting and combining prior art disclosures. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. For this reason, the combination of Hall and Pologe et al. is impermissible, and, consequently, that combination cannot render claims 2, 11, and 12 obvious to one of ordinary skill in the art. Accordingly, the

combination of Hall and Pologe et al. fails to render claims 2, 11, and 12 obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1-13, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

Although U. S. Patent No. 6,002,952 was not listed on the Form PTO-1449, U. S. Patent No. 6,002,952 is cumulative to U. S. Patent No. 6,067,462, because U. S. Application Serial No. 09/081,539, filed May 19, 1998, which became U. S. Patent No. 6,067,462, is a divisional application of U. S. Application Serial No. 08/834,194, filed April 14, 1997, which became U. S. Patent No. 6,002,952. Accordingly, it is submitted that the subject matter of U. S. Patent No. 6,002,952 has been considered, based on the consideration of U. S. Patent No. 6,067,462.

With respect to FIG. 12, FIG. 12 is not a photograph. FIG. 12 is a print formed from the image on a computer screen, which is equivalent to a print formed from any image on a computer screen, e.g., a print of this page as seen on a computer monitor. Accordingly, Applicants do not intend to file a petition for the acceptance of color drawings.

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